

No. 13-896

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IN THE  
**Supreme Court of the United States**

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COMMIL USA, LLC,  
*Petitioner,*  
v.

CISCO SYSTEMS, INC.,  
*Respondent.*

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**ON WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

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**BRIEF FOR AMICUS CURIAE ABBVIE INC.  
IN SUPPORT OF PETITIONER**

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## STATEMENT OF INTEREST

AbbVie Inc. develops innovative pharmaceutical treatments targeting a wide range of debilitating and life-threatening diseases.<sup>1</sup> Patent protection is integral to support AbbVie's investments in research and development, and the issue in this case—liability for those who induce infringement—particularly relates to many of AbbVie's technologies. AbbVie believes that the Federal Circuit's decision in this case incorrectly imposes a significant obstacle to enforcing patents against induced infringement and thus jeopardizes AbbVie's significant investments in its products and patents.

## SUMMARY OF ARGUMENT

Some of the most important inventions in modern medicine have come not from the synthesis of new drugs, but rather from the discovery that existing drugs can be used in new and different ways, to treat and cure different diseases than ever envisioned. Indeed, many breakthrough treatments for diseases such as cancer, leprosy, AIDS, and

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<sup>1</sup> Pursuant to Supreme Court Rule 37.6, AbbVie states that this brief was not authored, in whole or in part, by counsel for a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AbbVie or its counsel. Pursuant to Supreme Court Rule 37.3, counsel of record for all parties have consented to this filing.

multiple sclerosis involve the use of “old” drugs for new purposes. The patent laws recognize that these can be important inventions, and allow for method claims in the general form of “The method of treating Disease X using Compound Y.” Indeed, many of the most important patents in the pharmaceutical industry are written in this “method of use” format.

But it is impossible, as a practical matter, to enforce such patents by suing for direct infringement. After all, the only people who actually use Compound X to treat Disease Y are doctors and patients. But it would be both impractical and contrary to public policy for pharmaceutical companies to sue thousands of doctors and patients individually. Thus, where a competing drug company instructs doctors or patients to infringe, a patentee’s only possible recourse is to sue that company for indirect infringement. As such, the pharmaceutical industry is heavily dependent on a strong and meaningful doctrine of induced infringement. Otherwise, these critical method-of-use patents, which can represent hundreds of millions of dollars in investment, can be effectively meaningless.

The Federal Circuit’s *Commil* decision threatens to marginalize the value of these patents. Under that decision, a company may be able to escape liability for infringement even where the patent is found to be valid, and even where the company’s instructions unequivocally tell doctors and patients to practice the patented method, based solely on an incorrect belief that the patent was

invalid. That should not and cannot be correct. There is no doubt that the Federal Circuit's *Commil* decision will lead to increased reliance on opinions of counsel. But when a party instructs others to infringe a patent and where that patent is found to be valid, liability should attach. The Federal Circuit's decision should be reversed.

## ARGUMENT

### **I. The pharmaceutical industry depends on patents that may only realistically be enforced against indirect infringers.**

As an innovative pharmaceutical company, AbbVie relies on patent protection to help fund research and development of novel treatments in appreciation of patients' needs, including seven products currently in Phase III clinical trials intended to treat hematological and solid tumor cancers, multiple sclerosis, hepatitis C, and complications of diabetes, among others. Industry trends show that over seventy-five percent of pharmaceutical products in clinical trials do not even make it to market, and the expenses associated with those failures have to be compensated for by successful products. Joseph A. DiMasi, *The price of innovation: new estimates of drug development costs*, 22 J. Health Econ. 151, 165 (2003) (statistically analyzing 538 self-originated compounds that were first tested in humans between 1983 and 1994 for which information was available in the Tufts CSDD database and finding a clinical success rate of only 21.5%). Developing a treatment

to the point of marketability can take decades and incur costs in excess of two and a half billion dollars. Tufts Center for the Study of Drug Development, *Cost Study News Release* (Nov. 18, 2014), available at [http://csdd.tufts.edu/news/complete\\_story/pr\\_tufts\\_csdd\\_2014\\_cost\\_study](http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study); see also Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?* 28 *Manage. Decis. Econ.* 469, 477 (2007) (noting a capital cost of \$1.2B (year-2005 dollars) per approved new biopharmaceutical); DiMasi, *The price of innovation: new estimates of drug development costs*, at 180 (noting a capital cost of nearly \$900M (year-2000 dollars) per approved new drug, including post-approval research).

Patent protection provides a period of market exclusivity for undertaking such substantial investments. Because generic manufacturers simply copy successful pharmaceutical products, the significant risk and costs associated with researching and developing new therapeutics is eliminated. In contrast, companies that assume the risk and make the investment in discovery and development of innovative treatments rely on patent protection to support their investment and enable a return thereon, thereby supporting further investment in innovation. Maintaining its market often requires that a patent owner enforce its rights, and the patent-infringement statute permits a patent owner to enforce against either direct or indirect (contributory or induced) infringement. 35 U.S.C. § 271. Each prohibition addresses a distinct

conduct harming patent holders, thus establishing an overall scope of protection that Congress has deemed appropriate.

Many pharmaceutical patents may only be practically enforced by targeting those who induce infringement, because the patented technology is a method of treatment, rather than the basic compound used in the method. As explained below, because method-of-use patents—and preventing induced infringement of those patents, particularly in the context of the statutory mechanisms unique to the industry—critically affect the pharmaceutical industry, correcting the Federal Circuit’s erroneous holding in this case is exceptionally important.

**A. Many beneficial inventions take the form of methods of use of a known compound.**

Not uncommonly, innovations in disease treatment come from new applications for known compounds. In many such cases, a compound long known for, or thought overly risky in, certain applications may have beneficial, therapeutic uses when used in a new, innovative manner. Method-of-use patents protect those therapeutic uses and provide incentive to invest in the research required to develop them.

As an example, consider thalidomide, which was initially used to treat morning sickness. Tragically, this use of thalidomide led to widespread birth defects and infant fatalities. Subsequent research, however, suggested that thalidomide could

be used to treat leprosy and certain types of cancers, and today, thanks to extensive investment and rigorous clinical trials, thalidomide is an FDA-approved treatment for both multiple myeloma and the cutaneous manifestations of moderate to severe leprosy. Because thalidomide is an “old” compound, absent the exclusivity conferred by method-of-use patents, it is unlikely that innovative pharmaceutical companies would have undertaken the substantial research and development activities to bring these important treatments to market.<sup>2</sup> Indeed, the exclusivity gained through method-of-use patent protection has incentivized the pharmaceutical industry to develop important new uses for many other already known compounds, including, for example, azidothymidine (AZT, treating HIV, although first used decades earlier to treat cancer), botulinum toxin (treating urinary incontinence, muscle-spasm pain, headaches, and other neuromuscular disorders),<sup>3</sup> dimethyl fumarate

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<sup>2</sup> The FDA Orange Book lists patents applicable to each approved drug product (*see infra* at 21). The listing for thalidomide includes multiple method-of-use patents, including: 8,589,188; 8,315,886; 8,204,763; 7,959,566; 7,874,984; 7,435,745; 7,141,018; 6,908,432; 6,869,399; 6,755,784; 6,561,977; 6,561,976; 6,315,720; 6,045,501; and 5,629,327. *See* Orange Book listings for Application No. 020785, *available at* [http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl\\_No=020785&TABLE1=OB\\_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=020785&TABLE1=OB_Rx).

<sup>3</sup> Multiple method-of-use patents cover methods of using botulinum toxin in medical treatments, including: 6,667,041; 6,683,049; 6,896,886; 6,974,578; 7,001,602; 7,429,387;

(treating multiple sclerosis),<sup>4</sup> and arsenic trioxide (treating leukemia).<sup>5</sup> These are just a few examples of the many instances in which new treatments were developed for old compounds. *See also* Henry Grabowski, *Are the Economics of Pharmaceutical Research and Development Changing? Productivity, Patents and Political Pressures*, 22 *Pharmacoeconomics* (Supp. 2) 15, 21 (2004) (noting the difficult economic payback for investing in new drugs, and giving an example of an AIDS treatment protected only by method-of-use patents).

**B. Enforcing pharmaceutical method-of-use patents against direct infringers would strain public policy.**

Health-care providers or patients carrying out the steps of claimed methods of use typically act in

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7,449,192; 7,968,104; 8,057,807; 8,062,643; and 8,501,195. *See* Allergan Patent Notices, *available at* [http://www.allergan.com/products/patent\\_notices.htm](http://www.allergan.com/products/patent_notices.htm).

<sup>4</sup> The FDA Orange Book lists the following method-of-use patents for dimethyl fumarate: 7,320,999; 7,619,001; 7,803,840; 8,399,514; and 8,524,773. *See* Orange Book listings for Application No. 204063, *available at* [http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl\\_No=204063&Product\\_No=001&table1=OB\\_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=204063&Product_No=001&table1=OB_Rx).

<sup>5</sup> The FDA Orange Book lists the following method-of-use patents for arsenic trioxide: 6,723,351; 6,855,339; 6,861,076; 6,884,439; and 6,982,096. *See* Orange Book listings for Application No. 021248, *available at* [http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl\\_No=021248&Product\\_No=001&table1=OB\\_Rxt](http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021248&Product_No=001&table1=OB_Rxt).

accordance with instructions in the product labeling. *See, e.g., Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-55 (Fed. Cir. 2003). Enforcement against the direct infringers would create substantial problems and inefficiencies, eviscerating the value of method-of-use patents.

1. First, it would fail to target the entity economically benefiting from infringement—the generic pharmaceutical company selling a pharmaceutical product with the intention that it be used in an infringing manner. Additionally, it would be inefficient: it would require a piecemeal approach to address infringement, with separate cases having to be brought against each infringing physician or patient, resulting in multiplied transaction costs.

This Court has recognized that, when Congress established the indirect-infringement portions of § 271, it sought to codify the practice of protecting patent rights where enforcing against direct infringers is impractical. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 511-12 (1964) (*Aro II*) (citing H.R. 5988, 80th Cong., 2d Sess. (1948); H.R. 3866, 81st Cong., 1st Sess. (1949)); *cf. Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 929-30 (2005) (noting that indirect liability in copyright permits enforcement of rights when effectively enforcing against all direct infringers would be impossible); *see* Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 228 (2005) (noting the impracticality of enforcing pharmaceutical patents



with direct infringement). Indeed, as Commil points out (Commil Br. 31-33), one of the main drafters of the statute, Giles Rich, reminded a congressional subcommittee that “there may be twenty or thirty percent of all the patents that are granted that cannot practically be enforced against direct infringers because of the nature of the invention and the way it is claimed in the patent.” Statement of Giles Rich, Hearings before Subcommittee No. 3 of House Judiciary Committee on H.R. 3760, 82d Cong., 1st Sess., at 160.

2. Beyond the economic factors, public-interest considerations also militate against enforcing against direct infringement in the pharmaceutical context. Medical-technology companies like AbbVie invest in research to benefit patients and, while they do so with an aim of long-term profits, helping patients is a very real inspiration at the foundation of these companies. AbbVie respectfully submits that both physicians and patients should retain the freedom to pursue any approved treatment option without concern for patent-infringement liability. Congress has codified an attenuated version of this desire in 35 U.S.C. § 287(c), which precludes relief against medical practitioners performing medical or surgical procedures on patients.

Enforcing method-of-use patents through induced infringement, in contrast to direct infringement, avoids the piecemeal inefficiencies of multiple litigation actions, targets the party economically benefiting from the infringement, and

maintains patient access to all market options. Induced infringement is, in other words, a mechanism that neatly addresses conditions of the pharmaceutical market.

**II. The Federal Circuit’s “good-faith belief of invalidity” standard improperly unbalances enforcement of patent rights by conflating induced infringement with the more-stringent standard for willful infringement**

As Commil explains, the Federal Circuit’s rule does not comport with this Court’s precedent, the statutory structure, or other aspects of the law. Commil Br. 15-53. Moreover, as explained below, it also improperly raises the standard for induced infringement to be similar to that for willful infringement.

1. The patent statute defines induced infringement as one avenue Congress provided to enforce against infringement, 35 U.S.C. § 271, and provides a remedy of compensatory damages, 35 U.S.C. § 284. *See Aro II*, 377 U.S. at 512 (stating that “[t]he measure of recovery for patent infringement is governed by 35 U.S.C. § 284,” and applying it to contributory infringement); *see also id.* (“Hence we think that after a patentee has collected from or on behalf of a direct infringer damages sufficient to put him in the position he would have occupied had there been no infringement, he cannot thereafter collect actual damages from a person liable only for contributing to the same infringement.”).

Indeed, the creation and codification of a remedy for induced infringement simply provided an alternative enforcement mechanism for patent owners to target the most appropriate entity. *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 179-80 (1980) (“The idea that a patentee should be able to obtain relief against those whose acts facilitate infringement by others has been part of our law since *Wallace v. Holmes*, 29 F. Cas. 74 (No. 17100) (CC Conn. 1871).”); *Aro II*, 377 U.S. at 511-12 (noting Congress’s purpose in passing the indirect-infringement aspects of the current law). Thus, it stands to reason that the substantive requirements to prove inducement might not be expected to rise markedly above other enforcement mechanisms.

2. In addition to the compensatory damages available through any of the alternative forms of enforcement, the law also provides for enhanced damages when the nature of infringement is willful and thus justifies a punitive award. *See Aro II*, 377 U.S. at 508 (noting that “a case of willful or bad-faith infringement” may justify “punitive or ‘increased’ damages” in addition to “such damages as had actually been suffered from . . . contributory infringement”). The Federal Circuit interprets enhanced damages as requiring proof of willful infringement. *In re Seagate*, 497 F.3d 1360, 1368 (Fed. Cir. 2007). And enhanced damages are significant—they may as much as treble the compensatory award. 35 U.S.C. § 284.

To make the showing required for willful infringement, a patentee must prove both that “the infringer acted despite an objectively high likelihood that its actions constituted infringement of a *valid patent*,” and that this risk “was either known or so obvious that it should have been known to the accused infringer.” *Seagate*, 497 F.3d at 1371 (emphasis added). The punitive nature of the damages at issue arguably justifies those additional objective and subjective elements of willful infringement as compared to base infringement.

The Federal Circuit majority’s “good-faith belief of invalidity” exemption in *Commil*, however, introduces an infringer’s belief of invalidity into the basic test for induced infringement. This heightened level of intent was previously reserved for willful infringement. Without the punitive nature of awards for willful infringement, the justification for expanding the liability-eliminating role for invalidity falls away. Indeed, the Federal Circuit’s standard leaves little ground between the showing required for induced infringement and that required for willfulness.

**III. The Federal Circuit’s “good-faith belief of invalidity” exemption conflicts with the statutory framework and discriminates against pharmaceutical patent owners.**

As described above (*see supra* at 5-7), innovative medical treatments often take the form of new methods of using known compounds or formulations. The Federal Circuit’s rule in this case

hollows the core of enforcement by potentially eliminating infringement liability, at least up to the point of judicial determination of patent validity/infringement, and at the least incentivizing activities likely to cause irreparable harm. Thus, while the Federal Circuit may have crafted its rule with one case in mind, the rule conflicts with the statutory framework for pharmaceutical patents established by Congress and may lead to unintended consequences undermining valid patent rights.

**A. The Federal Circuit's standard could permit inducing parties to negate liability in the Hatch-Waxman context.**

Patent infringement in the pharmaceutical context often differs from other types of patent infringement as a result of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Act). The point of the framework set up by the Hatch-Waxman Act is to properly incentivize innovator manufacturers to develop new products, while at the same time incentivizing generic manufacturers to challenge patents and seek early entry. *See F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2228-29 (2013) (noting the incentive to generic manufacturers); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (noting the balancing incentives). This act reflects a carefully drawn balancing of incentives.

Under the Hatch-Waxman Act, the FDA publishes approved treatments in a document titled

Approved Drug Products with Therapeutic Equivalence Evaluations, known as the Orange Book. FDA, Approved Drug Products, *available at* <http://www.accessdata.fda.gov/scripts/cder/ob/>; *see also* 21 U.S.C. § 355(j)(7). The Orange Book entry for an approved drug includes a list of patents that the patent owner has provided as covering the approved treatment—expressly including method-of-use patents. *See* 21 U.S.C. § 355(j)(7)(A)(iii); 21 U.S.C. § 355(b)(1)(G); FDA, Approved Drug Products, Patent and Exclusivity Information Addendum.

When a generic manufacturer wishes to market a treatment equivalent to and relying upon an existing, approved treatment, the manufacturer may proceed with an Abbreviated New Drug Application (ANDA) under 21 U.S.C. § 355(j) (section 505(j) of the Hatch-Waxman Act). Filing an ANDA prior to expiration of the innovator company's Orange Book-listed patents is, by statute, an act of infringement. 35 U.S.C. § 271(e)(2). If the generic manufacturer wishes to sell its product before expiration of patents listed by the innovator company, it must certify that the listed patents are invalid or will not be infringed by the manufacture, use or sale thereof. 21 U.S.C. § 355(j)(2)(A)(vii) (known as a Paragraph IV certification).<sup>6</sup> It must

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<sup>6</sup> For method-of-use patents listed in the Orange Book, a generic manufacturer may also assert that the listed methods do not include the methods for which the manufacturer will label its product. 21 U.S.C. § 355(j)(2)(A)(viii).

also notify the patent owner of the factual and legal bases underlying the certification of noninfringement or invalidity. 21 U.S.C. § 355(j)(2)(B). The patent owner may then bring a claim for patent infringement, which triggers a thirty-month period during which the FDA will refrain from approving the ANDA, allowing the infringement suit to proceed. 21 U.S.C. § 355(j)(5)(B)(iii).<sup>7</sup>

Thus, under this framework, the patent holder may, and generally does, proceed with a patent suit in the district courts. *See* Michael A. Carrier, *Payment After Actavis*, 100 Iowa L. Rev. 7, 27 (2014) (noting 238 lawsuits from 2003 through 2009 alone). If the suit is complete by the end of the thirty-month stay period, little question remains regarding induced infringement at the time the generic manufacturer can market its treatment. If the generic manufacturer wins (either by proving noninfringement or invalidity), then—absent reversal on appeal—there can be no liability. If, on the other hand, the patent owner wins (the district court finds the patent infringed and not invalid), the generic manufacturer would clearly induce infringement by marketing the product and labeling it with instructions for practicing the claimed steps.

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<sup>7</sup> The first generic manufacturer to file an ANDA with a Paragraph IV certification is provided with a “180-day exclusivity period,” starting when the generic drug is first marketed, during which no other unauthorized generic drugs will be approved. 21 U.S.C. § 355(j)(5)(B)(iv).

However, in some cases, the thirty-month stay ends prior to a final decision by the district court. In such cases, the Federal Circuit's holding in *Commil* could open a door to infringement. When a generic manufacturer markets a treatment prior to a final court decision, it is said to launch the treatment "at risk." See *Sanofi-Aventis v. Sandoz, Inc.*, 405 F. App'x 493, 494 (Fed. Cir. 2010) (describing an at-risk launch as "a launch before a final court decision"). And such at-risk launches are not merely hypothetical, as shown by the *Sanofi-Aventis* case. See also Michael A. Carrier, *Payment After Actavis*, 100 Iowa L. Rev. 7, 27 (2014) (noting 28 at-risk launches out of 238 lawsuits involving first-filing Paragraph IV generic manufacturers from 2003 through 2009); Diane Christine Renbarger, *Putting the Brakes on Drugs: The Impact of KSR v. Teleflex on Pharmaceutical Patenting Strategies*, 42 Ga. L. Rev. 905, 936 (2008) (noting two such launches in 2006 and eight launches in 2007); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947, 957 (2011) (noting eight at-risk launches out of forty-nine drugs between 2005 and 2009). Importantly, as discussed below, the Federal Circuit's decision in this case would encourage such at-risk launches but reduce the actual risk thereof.

1. During this period of an at-risk launch—before the questions of infringement and validity are resolved by the courts—under the Federal Circuit's new rule, the generic manufacturer may seek to minimize its risk simply by obtaining an opinion of



counsel or proffering other evidence of its good-faith belief of invalidity, such as the detailed statement the generic manufacturer must send to the innovator company explaining the basis for its challenge to the listed patents. Because the patent owner has not yet prevailed in the district court, the generic manufacturer can profess that it does not believe the patent to be valid. Under the Federal Circuit’s “good-faith belief of invalidity” rule, an opinion of counsel that the patent is invalid, or potentially even the generic company’s Paragraph IV certification and explanation of bases alone, may provide sufficient basis on which an otherwise-inducing party can escape liability. *See* U.S. Br. on Pet. for Cert. 11-12 n.2 (noting that despite the Federal Circuit majority’s statement otherwise, operation of the rule seems to necessarily preclude liability).

Thus, the Federal Circuit’s rule could permit some generic manufacturers to escape inducement liability for a period of time until their invalidity arguments are rejected by a court, at which point their arguments would cease to support a good-faith belief. This would be an unjust result, particularly as the generic manufacturer would: know of the existence of the patent; know that the instructions it provides in its labeling correspond to the claimed steps of the patented method; and have ultimately failed to prove the patent was invalid.

2. Even if the risk of liability during an at-risk launch remains non-negligible, for example, because the “good-faith belief of invalidity” is only one aspect

of the inducement analysis, the Federal Circuit's rule improperly incentivizes an at-risk launch. Before the Federal Circuit's rule in this case, the potential reward of marketing a royalty-free treatment prior to court judgment already motivated generic manufacturers to launch at risk, as described above. The Federal Circuit's rule provides the added allure of increasing the likelihood of escaping liability for that period completely, even if the patent is directly infringed and valid. Moreover, while damages may still be available in some cases where the patent owner ultimately prevails, as explained in the following section, introduction of a royalty-free copy of a branded drug often causes irreparable harm to the patent owner, counseling against the incentive notwithstanding what damages may be available.

**B. Marketing of generic treatments, even if ultimately found to infringe, causes irreparable harm to patent owners.**

At-risk launches cause many harms to patent owners. For example, they can have disastrous effects on the market for a patented drug. In the first three months of generic treatments entering the market, a branded treatment can lose 75% of its market share. *See* Henry Grabowski, *Are the Economics of Pharmaceutical Research and Development Changing? Productivity, Patents and Political Pressures*, 22 *Pharmacoeconomics* (Supp. 2) 15, 19 (2004) (noting that the three largest branded treatments lost more than 75% market share in the

first quarter upon generic entry); *see also* John Hudson, *Generic Take-up in the Pharmaceutical Market Following Patent Expiry: A Multi-Country Study*, 20 Int'l Rev. L. & Econ. 205, 216 (2000) (determining that branded sales decline to 70% of the total after one year of generic entry); Atanu Saha et al., *Generic Competition in the US Pharmaceutical Industry*, 13 Int'l J. Econ. Bus. 15, 29-31 (2006) (observing a shift of 55% of sales volume to generics after one year of entry). A generic equivalent can largely replace sales of the branded compound because of 1) "generic substitution" laws; 2) incentives under which third-party payors drive patients to generic products; and 3) financial incentives that make the dispensing of generic drugs more attractive to pharmacists than dispensing the branded equivalent. *See* IMS Institute for Health Informatics, *The Use of Medicines in the United States: Review of 2010*, at 21-22 (2011), available at [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII\\_UseOfMed\\_report.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf).

Although loss of revenue might be recoverable through damages, at-risk launches create harm beyond just the direct reduction of revenue for a patent owner. One factor is price erosion: a branded drug cannot maintain its price after a generic has entered the market, even after that generic is no longer on the market. *See Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013) (reversing district court's finding of no irreparable harm, in part because it assumed that price erosion

and loss of market share were not irreparable); *see also Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (“Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm.”). Another factor is reduction in research: pharmaceutical research is often funded by revenue (rather than by debt or equity), so lost revenue from the sale of branded (patented) treatments negatively impacts research. *See, e.g., Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 609 F. Supp. 2d 786, 811-12 (S.D. Ind. 2009) (finding irreparable harm, in part, because of the “disruption or loss of research . . . as well as a scaling back of investment in research and development” that would result from the generic launch); *Bayer HealthCare, LLC v. FDA*, 942 F. Supp. 2d 17, 25-26 (D.D.C. 2013) (same). In other words, at-risk launches reduce the likelihood a company will seek out innovative uses for existing compounds.

Further, at-risk launches change patient copayments: a generic version of a branded drug may displace the branded drug as a preferred option for insurance companies, leading to higher copayments by patients. *See Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 342-43 (S.D.N.Y. 2006) (describing the phenomenon as a form of irreversible price erosion and finding irreparable harm); *see also Par Pharm., Inc. v. TWI Pharm., Inc.*, No. CCB-11-2466, 2014 WL 3956024, at \*4 (D. Md. Aug. 12, 2014) (finding irreparable harm, in part, due to displacement in formularies). Those copayments in

turn influence goodwill as the most direct aspect of many patients' differentiation between treatment options. Goodwill is also lost because of reduced reimbursement rates caused by market availability of a generic option. *See, e.g., Celsis*, 664 F.3d at 930 (“Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm.”). Finally, at-risk launches can cause other, difficult-to-quantify harm, such as the general shrinking of business operations and loss of jobs by the patent owner. *See generally Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008) (affirming the district court’s finding of irreparable harm and citing precedent holding that loss of revenue, market position, goodwill, research and development support, and market opportunities are evidence of irreparable harm).

In light of the multiple ways that at-risk launches can harm patent owners, particularly those harms irreparable though monetary damages, the incentive created by the Federal Circuit’s “good-faith belief of invalidity” should be eliminated.

## CONCLUSION

For the foregoing reasons, AbbVie respectfully requests that this Court overrule the Federal Circuit’s judgment.

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Respectfully submitted,

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